MISSOURI BOARD OF PHARMACY

NEWSLETTER

FEBRUARY 2019

CONTENTS

NEW BOARD MEMBERS

Congratulations to our newest Board members appointed by Governor Parson:

James L. Gray, Pharm.D., MBA

Original Appointment: 12-14-18
Term Expires: 6-1-22

James L. Gray III, PharmD, MBA is currently Executive Director of Pharmacy at Barnes-Jewish Hospital, a position he has held since 1983. From 1988 to 1995 Dr. Gray also served as the administrative director for transplant programs at Barnes-Jewish Hospital. From 1979 to 1983 Dr. Gray held clinical and administrative positions at LifeMark Pharmacy Management in Houston, TX and from 1977 to 1979 was an assistant professor at the Ohio State University College of Pharmacy. Dr. Gray received a BS in pharmacy from the University of Pittsburgh in 1975. He earned a PharmD at Duquesne University and completed an ASHP accredited residency in pharmacy practice at Mercy Hospital, Pittsburgh, in 1977. He completed his MBA at Washington University in 2001. He is a member of the American Society of Health-System Pharmacists, Missouri Society of Health System Pharmacists, Missouri Pharmacy Association and National Association of Boards of Pharmacy. He is a past recipient of the Missouri Society of Health System Pharmacists Research and Education Foundation's Thomas J. Garrison Achievement Award and is previously served on the Board from 1997 to 2002.

Colby Grove, Pharm.D., Member

Original Appointment: 12-14-18
Term Expires: 6-1-22

Colby Grove holds Bachelor's degrees in Chemistry and Biology, and minors in Business and Global Studies from Drury University. He received his Doctorate of Pharmacy from Lake Erie College of Osteopathic Medicine School of Pharmacy. Dr. Grove is owner of The Pharmacy @ Pleasant Hope as well as Ash Grove Pharmacy, Inc. The pharmacies offer prescriptions services, compounding, immunizations, and long term care services. During his career he served as an intern for the Professional Compounding Centers of America, Mercy and Cox Hospitals before working at Walgreens and CVS Pharmacy. Dr. Grove is currently active in both the Missouri Pharmacists Association (MPA) and National Community Pharmacists Association (NCPA). Colby is a third generation pharmacist as well as a third generation pharmacy owner from a family of ten pharmacists dating back to the early 1900's. His great uncle, grandfather, father, mother, and uncle have all owned independent pharmacies across the Midwest. It is because of his family history that Colby has formed a lifelong passion for community pharmacy.

THANK YOU!

The Board would like to extend its thanks and gratitude to Dr. Barbara Bilek for her dedicated service to the Board and the citizens of Missouri. Barbara Bilek was originally appointed to the Board on June 7, 2007 and served as the Board's hospital representative until her recent retirement in 2018.

Barbara received her Bachelor of Science degree in 1972 and Doctor of Pharmacy degree in 1990 from the University of Illinois at Chicago Medical Center College of Pharmacy. Barbara was subsequently licensed as a pharmacist in Missouri, Illinois and California. Dr. Bilek started her pharmacy career at Little Company of Mary Hospital, Evergreen Park, Illinois, where she worked as a staff pharmacist, oncology clinical pharmacist, and QA Coordinator. She then became assistant director at the University of Illinois Hospital, and also served as clinical assistant professor at the University of Illinois at Chicago Medical Center College of Pharmacy.

Prior to her retirement, Dr. Bilek served as Pharmacy Director at Mosaic Life Care (formerly Heartland Regional Medical Center) in St. Joseph, Missouri. Barbara was a strong voice for hospital practice and a staunch patient safety advocate. Thank you Barbara for your service to the pharmacy community and happy travels during your retirement!

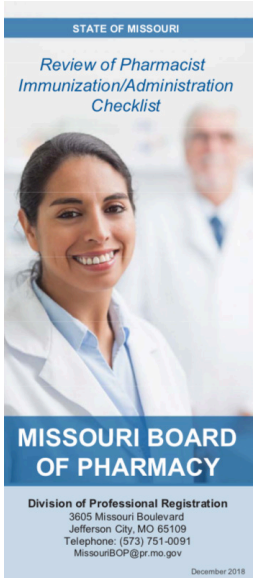
IMMUNIZATION CHANGES

As winter weather settles in, pharmacists play a key role in keeping Missourians healthy. The Board recently revised 20 CSR 2220-6.050 (Immunization by Protocol) to streamline Missouri's immunization requirements:

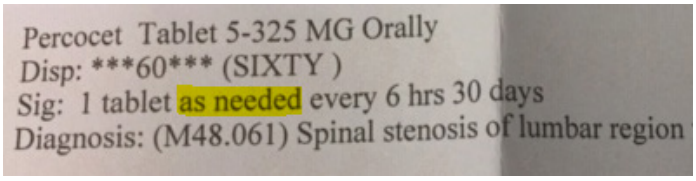
	✗ Old Rule	✓ New Rule
Mileage Limits	Protocol physician must be within 50-mile radius	No mileage restrictions
Minimum Patient Age	12 years old with no exceptions	The minimum age authorized by law which is currently seven (7) years old or the age recommended by the Centers for Disease Control and Prevention, whichever is higher (unless otherwise restricted by protocol). [§ 338.010]
Authorized Immunication Locations	All immunization locations must be listed in the protocol	Immunization allowed at any Missouri licensed pharmacy. Only non-pharmacy sites have to be listed in the protocol.
Notifications of Intent	Annual renewal required	Must be renewed every two (2) years with your Missouri pharmacist license.
Vaccine Notifications	Protocol physician must be notified within 72-hours.	Protocol physician must be notified as designated in the governing protocol; No minimum time limit set by rule. *Notification of adverse events still required within 24 hours.
Continuing Education	Two (2) hours of CE required annually	Two (2) hours of CE required each biennial renewal period (11/1 of even numbered years to 10/31 of even numbered years).

Pharmacists should check and update their protocols to make sure the protocol includes/allows the rule changes such as the lower immunization age. Compliance with your protocol is mandatory even though the rule has changed.

Licensees should review 20 CSR 2220-6.050 for a complete listing of the updated requirements. The Pharmacist Administration/ Immunization Checklist brochure has also been updated and is available on the Board's website.



"PRN" DOES MATTER



As part of the inspection process Board inspectors review prescriptions for dispensing accuracy. When a discrepancy is discovered, the inspector issues a Quality Assurance Report that asks the pharmacist-in-charge to investigate the discrepancy. The most common discrepancy that inspectors find involves "PRN" in the label directions. Either "as needed" is omitted from the label directions when prescribed as "PRN" or "as needed" is included in the label directions when not prescribed as "PRN".

While this may seem minor, the inclusion or exclusion of "PRN" can be clinically significant. "PRN" directs the patient to either take the medication on a scheduled basis regardless of symptoms or on a more limited basis based when needed. The omission/inclusion of "PRN" may be especially important with opiates in light of the ongoing opioid crisis. Omitting "PRN" may direct the patient to take more medication than actually needed which could lead to dependency.

Pharmacists should pay careful attention when verifying medication to make sure the prescribed directions are correct.

BOARD MEETING UPDATES:

The Board held its winter meeting on January 10-11, 2019. The Board is requesting public comments on the following items that are currently under review:

1) Temperature Controls for Medication Delivery: The Board held a public listening session at its January 2019 meeting on temperature control/monitoring requirements for medication delivery. The Board will be conducting additional research and reconsidering this issue at its April 2019 meeting.
2) Chapter 338 Review: The Board will be reviewing Chapter 338, RSMo, to update and modernize pharmacist scope of practice. The goal of the review is to identify ways to increase access to care and enhance patient safety while empowering pharmacists to maximize their clinical skill and training. Legislative proposals would be subject to the Governor's approval for filing during the 2020 legislative session.
3) Class-O Automated Dispensing System (Ambulatory Care): The Board is considering rule options to allow automated dispensing systems in an ambulatory setting. The Board will be conducting additional research and is requesting feedback on how a potential rule might impact small businesses. The rule proposal will be reviewed again at the April 2019 meeting.

Interested parties may submit feedback/suggestions to MissouriBOP@pr.mo.gov. Comments should be submitted before March 15, 2019, to allow adequate review time before the April meeting.

UPCOMING BOARD MEETINGS:

FEB 13 — Conference Call

APR 10-11 — Columbia, Missouri

JUL 10-11 — Columbia, Missouri

NOTES ON TECHNICIAN APPLICATIONS

The office has recently received calls from supervising pharmacists and pharmacy technicians indicating that a technician applicant will be terminated or released from employment if their pharmacy technician registration isn't issued by the Board within a designated timeframe.

The Board receives more than 5,000 new pharmacy technician applications a year. Most registrations are processed and issued in less than 7 days. However, the Board receives a significant number of incomplete applications that have to be returned to the applicant for additional information. The majority of incomplete applications are delayed because:

- The application isn't signed
- Not all questions are answered/Illegible responses
- The technician's check or money order isn't signed
- Multiple boxes are checked for the same question
- A 2 x 2 photograph isn't attached
- Verification of a name change is needed
- Outstanding fees owed to the Board
- Verification of employment start date (applicants may only begin working as technicians once a completed application is filed), or criminal history

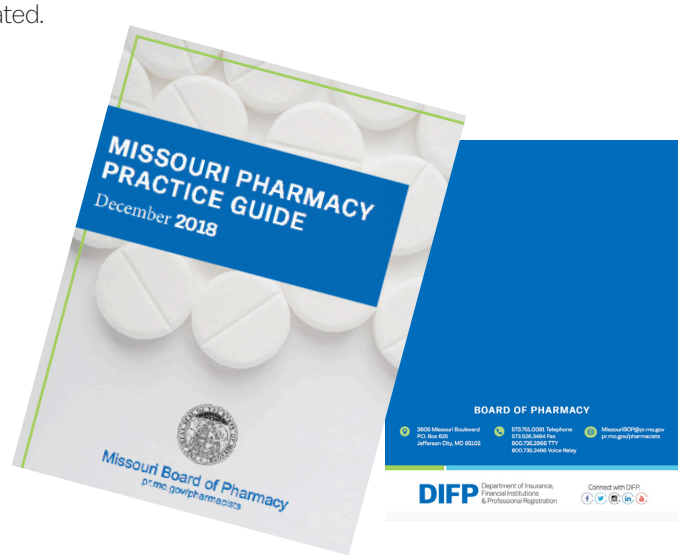
Applicants who are asked for additional criminal history information may not have been convicted of a crime. For example, an applicant may have a criminal charge that was withdrawn or dismissed but a dismissal/closing date is not listed in the criminal history report. Applicants may be asked to verify the case disposition before being approved although there wasn't a conviction.

For applicants with criminal history, not every criminal charge will result in the applicant being denied or being placed on the Employment Disqualification List. The Board reviews each application on a case-by-case basis and will look at relevant evidence such as the nature/circumstances of the criminal charge, evidence of rehabilitation and current work history. Federal and state law prohibit the Board from disclosing criminal history information without the applicant's consent. The Board can provide general information on the status of an application but cannot discuss criminal history information with an employer or PIC without the applicant's authorization.

Avoid processing delays by making sure applications are complete and accurate.

UPDATED PHARMACY PRACTICE GUIDE NOW AVAILABLE:

The revised Missouri Pharmacy Practice Guide is available now on the Board's website. The Practice Guide CE quiz has also been updated.



CONGRATULATIONS!

The Board would like to extend its congratulations to the following pharmacists and recognize their outstanding contributions to Missouri pharmacy practice:

WILLIAM A. "FITZ" FITZPATRICK, R.PH.

William has served as a dedicated Missouri licensed pharmacist on both the state and national level. Fitz, as he is best known by the countless friends he's gained over his 50+ years in the pharmacy profession, earned his B.S. in pharmacy from St. Louis College of Pharmacy in 1965. Fitz was inducted into the Kappa Psi Fraternity and later served as National President (Grand Regent) from 1974-1979 and Executive Director from 1971-1973.

After graduating from pharmacy school, Fitz served in a variety of leadership roles such as:

- Supervisor, Barnes Hospital (1965-1967)
- Pharmacy Manager, Kean Drug (1967-1969)
- Director of Pharmacy Operations, Schnucks Markets, Inc. (1969)
- Nursing Home Administrator, St. Louis Geriatric Center (1970)

Fitz had the distinct honor of opening up his own retail pharmacy, Fitzpatrick Pharmacy, in 1971 that he maintained until 1997. In his final years of practice, Fitz served as Vice President of

Interlock Pharmacy Systems, Inc. from 1989-1998 and Corporate Compliance Officer for Omnicare, Inc., (1997 – 2009) when it provided services to 1.4 million residents of skilled nursing, assisted living, and other healthcare facilities located in 47 states and Canada. Fitz was responsible for compliance training for all of Omnicare's 18,000 employees in addition to working with federal and state agencies on regulatory issues.

Fitz was appointed to the Missouri Board of Pharmacy in 1989 where he proudly served until 1997. He was elected as Board president for 5 consecutive years (1992 – 1997) which is still a Board record! In addition to his service to the Board, Fitz was active in advancing pharmacy at the national level. Fitz began his membership with National Association of Boards of Pharmacy (NABP) in 1989 where he maintained an active role until 2018. He was named NABP Honorary President 2005-2006 for his service to public health, his dedication to NABP and the boards of pharmacy and his unshakable commitment to patient care. During his 30 year NABP membership, Fitz attended all of the national and district meetings with the exception of only 2.

Fitz has won multiple local, state and national awards, however, he is most proud to be the father of five beautiful daughters, 6 granddaughters, 6 grandsons and 1 great grandson. After living in Missouri for 57 years, Fitz now resides in Granbury, Texas to be close to his family.

BERT MCCLARY

If there was a "Pharmacy Hall of Fame," Bert McClary would be at the top of the list! Over his 50-year pharmacy career, Bert has been an unwavering force in advancing pharmacy practice, modernizing Missouri regulation and enhancing patient care.

Bert graduated from UMKC- Pharmacy School in 1966 where he interned at both Lakeside Hospital and Long's Drug Shop in Boonville, Missouri. After graduating from pharmacy school, Bert continued working in both retail and hospital pharmacy serving as a staff pharmacist at Long's Drug Shop and as a consultant pharmacist at Cooper County Memorial Hospital. Bert went on to serve as staff pharmacist at the University of Missouri Hospitals and Clinics in Columbia, Missouri where he was eventually promoted to Assistant Director of Pharmacy Services. While at University Hospital, Bert developed the first sterile compounding service in Missouri outside of St. Louis/Kansas City. Bert was also a charter member of the Missouri Society of Health-System Pharmacists (formerly the Missouri Society of Hospital Pharmacists) and served on MSHP's first organizational planning committee.

Perhaps one of Bert's greatest professional achievements has been his undeniable impact on shaping Missouri pharmacy law. Bert began his regulatory career in 1988 when he joined the Missouri Bureau of Narcotics and Dangerous Drugs as a Pharmacist Consultant and Assistant Administrator. Bert was subsequently named Pharmacist Consultant for the Missouri Department of Health and Senior Services (DHSS) where he advised all of the DHSS divisions/agencies. While with DHSS, Bert played a critical role in creating and shaping Missouri's pharmacy laws, including drafting/collaborating on:

- Missouri's hospital, long-term care, home health and hospice licensing rules
- BNDD's controlled substance rules (1993)
- Missouri's Strategic National Stockpile and DHSS drug distribution rules and
- Missouri's hospital medication management rules (1995).
- Bert also created a number of statewide policies and guidelines such as:
- Missouri Association of Anesthesiologists hospital CRNA protocols
- Missouri State Prison medication guidelines
- Department of Elementary and Secondary Education school health manual
- DHSS Certified Medication Technician training manual, and
- DHSS Local Public Health Manual

Over the years, Bert has served as a trusted advisor to the Board of Pharmacy where he has been a consistent voice for empowering pharmacist activities while vigilantly safeguarding patient care. Bert served as a founding member of the Missouri Hospital Advisory Committee and assisted on a variety of Board committees and working groups including the:

- Pharmacy Technician Working Group
- Patient Safety Working Group, and
- Medication Therapy Services Advisory Group

Bert's contributions to Missouri pharmacy practice have built a lasting legacy that has made Missouri better, stronger and safer.

Thank you Fitz and Bert for your contributions to the Board and Missouri pharmacy practice. Congratulations on your retirements!

GOLD CERTIFICATES

Congratulations to our newest "gold certificate" pharmacists who will have maintained a Missouri pharmacist license for 50 years as of March 31, 2019:

Benny E Thomas
Russell M Donnell
Steven E Hartwig
Henry T Hayden
Ronald V Keeler
Samuel W Kernohan
William A Rall
Gerald A Sobel
Dennis G Tilly
Frederick E Tonnies Jr.
Barry J Naeger
Robert A Suschnick
James E Tilghman
Robert S Zucco
Patrick E Magee
Clayton F McCruden
David R Stevenson
Melvin R Bird
Frank D Farrell
Lillie L Smith
Morris P Deewall
William E Maleski
John T Price
Dale L Stafford
Peggy J Shuman
Richard L Poore
William Weeks III

OPIOID DISPENSING

Missouri pharmacists are often on the frontline of combatting the opioid crisis. Verifying that a controlled substance prescription is legitimate or within authorized supply limits can be a difficult task, especially for new pharmacy patients. Pharmacists must comply with their corresponding responsibility to ensure the validity of controlled substance prescriptions. Pharmacists should also ensure legitimate patients are not unduly denied or delayed access to pain medication when appropriate. A few notes:

- Don't be afraid to ask! Call the prescriber if you have questions or need a clarification. Talk with the patient and explain additional information is needed.
- Rigid metrics with no room for variation may unduly interfere with patient treatment. Instead, each prescription should be reviewed on an individual basis in light of the patient's specific medical needs and treatment.
- Professionalism still matters: Communicate professionally and courteously if you decide a prescription should not be filled. Patients may be in pain or may not understand why their medication isn't being dispensed. Remember, you are the professional!

DISCIPLINARY ACTIONS

DRUG DISTRIBUTORS

- Nurse Assist, #2018026599, Haltom City, TX. Probation for two (2) years. Failed to renew the previous drug distributor license; continued shipping legend medical devices into Missouri for approximately two (2) years. Section 338.055.2 (6) RSMo.
- Pro Med, #2006036798, Palmyra, MO. Probation for three (3) years. Purchased unapproved drugs from unlicensed drug distributors. Section 338.055.2(5), (6), (10), (13), and (15), RSMo.
- Respiratory Services and Solutions III LLC, #2017042033 Barnhart, MO. Probation for three (3) years. Operated with an expired license. Section 338.055.2(5), (6), (13), and (15) RSMo.
- Veterinary Nutritional Services, #2013012639, Mitchell, SD. Probation for three (3) years. Purchased unapproved drugs from unlicensed drug distributors. Section 338.055.2(5), (6), (13), and (15), RSMo.

PHARMACISTS

- Ajibola, Idowa, #2000148442, Florissant, MO. Probation for three (3) years. As Pharmacist-in-Charge, pharmacy had multiple inspection violations, dispensing errors, outdated drugs in active inventory, controlled substance violations, failure to maintain proper sanitary conditions, missing/ incomplete policies and procedures, Section 338.055.2 (5), (6), (13), (15), and (16) RSMo.

- Bishr, Laurie K., #2017011703, Roeland Park, KS. Public Censure. Administered immunizations without a current signed protocol. Section 338.055.2 (5), (6), (13), and (15) RSMo

- Dryer, Tracy D, 042208, Blue Springs, MO. Probation for two (2) years. Compounded prescriptions with expired ingredients, dispensed compounded medications exceeding the amount authorized by the prescriber, failed to maintain proper records. Section 338.055.2(5), (6), (13), and (15), RSMo.

- Felts, Kathryn J., #2007014735, Overland Park, KS. Public Censure. Administered immunizations without a current signed protocol. Section 338.055.2 (5), (6), (13), and (15) RSMo

- Garcia, Jesse M., Kingwood, TX Probation for five (5) years. Created prescriptions for controlled substances without physician authorization, called them into another pharmacy to pick up. Section 338.055.2 (5), (6), (13), (15) and (17), RSMo.

- Geers, Christina, #041909, Ashland, MO. Probation for two (2) years. As Pharmacist-in-charge, failed to maintain a valid Combat Methamphetamine Act self-certification, failed to record the sales of pseudoephedrine containing products using the real-time electronic pseudoephedrine tracking system. Section 338.055.2 (5), (6), (13), and (15) RSMo.

- Gore, Brittany K., #2011026578, Olathe, KS. Public Censure. As Pharmacist-in-charge, administered immunizations without a current signed protocol and allowed staff pharmacists to administer immunizations without a current signed protocol. Section 338.055.2 (5), (6), (13), and (15) RSMo.

- Grover, Tiffany D. #2018032233, Maryland Heights, MO. Probation for three (3) years. Plead guilty to unlawful possession of a controlled substance, a felony in 2016. Section 338.055.1 and .2 (2), (15), and (17) RSMo.

- Hart, Karen., #2011026578, Belton, MO. Public Censure. Administered immunizations without a current signed protocol. Section 338.055.2 (5), (6), (13), and (15) RSMo.

- Hawse, David R., #040709, Manchester, MO. Probation for three (3) years. Tested positive for marijuana on an employer drug screen. Section 338.055.2(13), and (15) RSMo.

- Karrenbock, Ann L., #042496, Kansas City, MO. Public Censure. Administered immunizations without a current signed protocol. Section 338.055.2 (5), (6), (13), and (15) RSMo.

- Kent, Jason A., #2014036348, Olathe, KS. Probation for five (5) years. As staff pharmacist, diverted with the intent to sell Xanax, clonazepam, and Soma from the pharmacy without a valid prescription. Failed to disclose prior controlled substance use on licensure applications. Section 338.055.2 (3), (4), (5), (13), (15) and (17), RSMo.

- Klein, Douglas C., #044202, Lees Summit, MO. Public Censure. As pharmacist-in-charge, allowed pharmacy technicians to work unsupervised. Pharmacy failed to have Class J license and failed to follow Class J requirements. Section 338.055.2 (5), (6), (13), and (15), RSMo.

- Manasseh, Fredrick N., 2007019773, Overland Park, KS. Public Censure. Administered immunizations without a current signed protocol. Section 338.055.2 (5), (6), (13), and (15) RSMo.

- Martin, Roy A., 2007035593, Oklahoma City, OK. Probation to end June 15, 2021 Out-of-State Order for sterile compounding violations. 338.055.2(5), (6), (13), and (15) RSMo.

- Plein, Michael A., #028950, Brentwood, MO. Probation for two (2) years. As pharmacist-in-charge, allowed a technician to administer vaccinations by medical prescription order and protocol, pharmacist failed to file a notification of intent by protocol, administration recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

- Rowland, Bradley K., #041988, Sedalia, MO. Public Censure. As Pharmacist-in-charge, submitted inaccurate billing information. Failed to keep accurate dispensing records. Section 338.055.2 (4), (5), (6), (13), and (15) RSMo.

- White, Russell L, #2001024200, Springfield, MO. Probation for five (5) years. Pled guilty to multiple driving while intoxicated charges. Section 338.055.2 (3), (5), (13), and (15), RSMo.

PHARMACIES

- Ashland Pharmacy, #005676, Ashland, MO. Probation for two (2) years. Failed to maintain a valid Combat Methamphetamine Act self-certification, failed to record the sales of pseudoephedrine containing products using the real-time electronic pseudoephedrine tracking system. Section 338.055.2 (5), (6), (13), and (15) RSMo.

- Key Pharmacy, #2008019160, Federal Way, WA Probation for one (1) year. Multiple FDA inspection violations, voluntarily recalled certain sterile compounded drugs, out-of-state discipline for compounding and dispensing violations, continued to ship recalled products into Missouri. Section 338.055.2 (5), (6), (13), and (15)

- Omnicare Pharmacy of the Midwest d/b/a Omnicare of Kansas City, #2006009026, Kansas City, MO. Public Censure. The pharmacy failed to provide effective controls and procedures to guard against the theft of controlled substances. Section 338.055.2 (6), (13), and (15) RSMo.

- Rehoboth Pharmacy, #2007000836, Florissant, MO. Probation for three (3) years. Multiple inspection violations. Dispensing errors, outdated drugs in active inventory, controlled substance violations, failure to maintain proper sanitary conditions, policies and procedures, Section 338.055.2 (5), (6), (13), and (15)

- Walgreens #04466, #006438, St. Joseph, MO. Probation for three (3) years. Multiple inspection violations, failure to maintain proper policies and procedures, multiple compounding violations. Section 338.055.2 (6), and (15)

- Walgreens #07551, #2003014789, St. Joseph, MO. Probation for three (3) years. Multiple inspection violations. Failure to maintain proper policies and procedures, multiple compounding violations. Section 338.055.2 (6), and (15)

Sign up for the Board's e-alerts for updates on regulatory changes, disciplinary actions, technician disqualifications and HB 600 (tax) suspensions. Subscribe online at https://public.govdelivery.com/accounts/MODIFP/subscribers/new?preferences=true.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - 1ST QUARTER 2019

(The following information was provided by the National Association of Boards of Pharmacy and is reprinted with permission of NABP. This information is provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.)

FINAL GUIDANCE DOCUMENTS ADDRESS FDA POLICIES RELATED TO DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- Product Identifier Requirements Under the Drug Supply Chain Security Act Compliance Policy addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.

FIRST FDA-APPROVED DRUG CONTAINING EXTRACT FROM CANNABIS PLANT TO BE PLACED IN SCHEDULE V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at www.dea.gov/press-releases/2018/09/27/ fda-approved-drug-epidiolex-placed-schedule-v-con- trolled-substance-act.

ASHP GUIDELINES PROVIDE RECOMMENDATIONS FOR PREVENTING PATIENT HARM FROM MEDICATION ERRORS

New guidelines from the American Society of Health System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the American Journal of Health-System Pharmacy, the guidelines are available at www.ajhp.org/content/75/19/1493. ASHP's October 2, 2018 press release can be found in the News section at www.ashp.org.

FDA'S FINAL GUIDANCE DOCUMENTS ADDRESS COMPOUNDING AND REPACKAGING OF RADIOPHARMACEUTICALS

On September 26, 2018, FDA published the final guidance titled Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities. In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the Federal Register notice at www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.

At the same time, FDA published the final guidance titled Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities. This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the Federal Register notice at www.gpo.gov/fdsys/pkg/FR- 2018-09-26/pdf/2018-20902.pdf.

PHARMACY TOOLKIT ENCOURAGES CONVERSATIONS WITH PATIENTS ABOUT PRESCRIPTION OPIOIDS

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at https://againstopioidabuse.org.

BIOSIMILARS ADDED TO FIP'S POLICY ON PHARMACISTS' RIGHT TO SUBSTITUTE A MEDICATION

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at www.fip.org in their respective sections.

FDA OFFERS CE COURSE ON REDUCING HYPOGLYCEMIC EVENTS IN PATIENTS WITH TYPE 2 DIABETES

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes, will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit http://fdapasediabetes.e-paga.com.

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.